

Docket No. TIP9015US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Hendrika et al.

Serial No. : 10/519,436

Art Unit: 1648

Filed

: December 22, 2004

Examiner: Humphrey, L.W.Z.

For

: NEW MUTATIONAL PROFILES IN HIV-1 REVERSE TRANSCRIPTASE CORRELATED WITH PHENOYPIC DRUG

RESISTANCE

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Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

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not in the	The relevance of those listed references which are English language is as follows:
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correspond	ing patent application(s), which are listed on the
attached S	Submission Under MPEP 609 D.
patent app	Attached are the following non-published pending clications which may be deemed relevant, which are the attached Submission Under MPEP 609 D.
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	Respectfully submitted,
	\Yunling Ren_ Yunling Ren Reg. No. 47,019 Attorney for Applicants

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (732) 524-3385 DATED: June 27, 2007 PTO/SB/08A (08-00)
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Sheet 1 of 3

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327,742

a collection of information unless it displays a valid OMB control number.		
Application Number	10/519,436	
Filing Date	12/22/2004	
First Named Inventor	Hendrika	
Group Art Unit	1648	
Examiner Name	Humphrey, L.W.Z.	
Attorney Docket Number	TIP0015US	

U.S. PATENT DOCUMENTS

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Date of Publication of Cited Document where relevant passages or relevant figures appear

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FOREIGN PATENT DOCUMENTS

		Foreign	Patent Documer	nt	Name of Patentee or	Date of Publication of Cited Document	Pages, Columns, Lines, where relevant	
Examiner Initials	Cite No. ¹	Office ³	Number⁴ Kir	ndCode ⁵	Applicant of Cited Document	mm-dd-yyyy	passages or relevant figures appear	T ⁶
		EP	406985	A 2	Janssen Pharmaceutica,N.V.	01/09/1991		
		wo	97/27319	A1	Virologic, Inc.	07/31/1997		
		EP	428000	A1	Abbott Laboratories	05/22/1991		
		PCT	97/27332	A1	Innogenetics,N.V.	07/31/1997		
		PCT	97/27480	A1	Virco,N.V.	07/31/1997		
		РСТ	99/67428	A2	Innogenetics N.V.	12/29/1999		
		PCT	00/73511	A1	Virco NV	12/07/2000		
		PCT	00/78994	A1	The Penn State Research Foundation	12/28/2000		
		PCT	00/78996	A1	Virologic, Inc.	12/28/2000		
		wo	01/79540	A2				
_		PCT	01/81624	A1	Virco N.V.	11/01/2001		
		PCT	01/95230	A2	Virco UK Limited	12/13/2001		
		PCT	02/083657	A2	Tibotec Pharmaceuticals Ltd.	10/24/20002		
		PCT	02/22076	A2	Virologic, Inc.	03/21/2002		
		PCT	02/33402	A 2	Virco N.V.	04/25/2002		
		PCT	02/38792	A2	Biolliance Pharma	05/16/2002		
		РСТ	04/022523	A2	Elan Pharmaceuticals, Inc.	03/18/2004		

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Examiner Name	Humphrey , L.W.Z		
Attorney Docket Number	TIP0015US		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner's	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
initials	NO.	ABSTRACT: International Congress on Drug Therapy in HIV Infection, Volume	
		12,Supplement 4, AIDS.online.com	
		ABSTRACT: Comprehensive HIV Drug Resistance Monitoring Using Rapid,	
		High-Throughut Phenotypic and Geotypic Assays with Correlative Data	
		Analysis. Poster Abstracts, OP3.4	
	-	Condra, Jon ., et al. Genetic Correlates of InVIvo Viral Resistance to Idivavir,a	
		Humanimmunodefieiency Virus Thee 1 Protease Inhibitor. Journal of Virology,	
		December 1996, pp. 8270-8276	
		GUIDANCE FOR INDUSTRY. U.S. Department of Health and Human Services,	
		Food and Drug Administration	
		Eastman, P. Scott, et al. Nonisotopic Hybridization Asay for Determinatin of	
		Relative Amounts of Genotypic Human Immunodeficiency Virus Tpe 1	
		Zidovudine Resistance. Journal of Clinical Microbiology, Oct. 1995, pp. 2777-2780	
		Eriksson, Bertil F.H., et al. Phosphorylation of 3'-Azido-2',3'-Dideoxyuridine and	
		Preferential Inhibition of Human and Simian Immunodeficiency Virus Reverse	
		Transcriptases by Its 5'-Triphosphate. Antimicrobial Agents ad	
		Chemotherapy, Oct 1989, pp. 1729-1734	
		Fodor, Stephen P.A., et al. Multiplexed Biochemical Assays With Biological	
		Chips. Nature, August 5, 1993, Vol. 364, pp. 555-556	
		Harada, Shinji, et al. Infection of HTLV-III/LAV in HTLV-I-Carring Cells MT-2	
	1	andMT-4 andApplicationin a Plaque Assay. Department o Virology and	
		Prasitology, Yamaguchi University, Japan, august 9, 1985, p. 563-566	
		Hertogs, Kurt, et al. A Rapid Method for Simultaneous Detection of Pheotpic	
		Resistance to Inhibitors of Protease and Reverse Transcriptase in	
		Recombinant Human Immunodeficiency Virus Type 1 Isolates from Patients	
		Treated with Antiretroviral Drugs. Antimicrobial Agents ad Chemotherapy,	
		February 1998, pp. 269-276	
	•	Ibanex, Angela, et al. Human Immunodeficiency Virus Type 1 Population	
		Bottleneck During Indinavir Theraphy Causes a Genetic Drift in the env	
		quasispecies Journal of General Virology, 2000, p. 85-95	
		Konig, Herbert, et al. Azidothymidine Triphosphate Is an Inhibitor of Both	
		Human Immunodeficiency Virus Type 1 Reverse Transcripatse and DNA	
		Polymerase Gamma. Antimicrobial Agents and Chemotherapy, December 1989,	
		pp. 2109-2114	<u> </u>
		Larder, Brendan A., et al. Zidovudine Resistance Predicted by Direct Detection of Mutations in DNA from HIV-infected Lymphocytes. AIDS, 1991, 5:137-144	
	 	Larder, Brendan A., et al. HIV with a Reduced Sensitivity to Zidovudine (AZT)	
		Isolated During Prolonged Therapy. Reports, March 31,1980, pp. 1731-1734	
	-	Lennerstrand, J., et al. A Method for Combined Immunoaffinity Purification and	
		Assay of HIV-1 Reverse Transcriptase Activity Useful for Crude Samples.	
		Analytical Biochemistry 235, 1996, pp.141-152	

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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10/519,436
12/22/2004
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Humphrey, L.W.Z
TIP0015US
1

Matayoshi, Edmund D., et al. Novel Flurogenic Substrates for Assaying	
Retroviral Proteases by Resonance Energy Transfer. Science, Vol. 247, pp.	
954-958	
Miller, Veronica, et al. Patterns of Resistance and Cross-Resistance to Human	
Immunodeficiency Virus type 1 Reverse Transcriptase Inhibitors in Patents	
Treated with the Nonnucleoside Reverse Transcripatse Inhibitor Loviride.	
Antimicrobial Agents ad Chemotherapy, December 1998, pp. 3123-3129	
Rusconi, Stefao, et al. Susceptibility to PNU-140690 (Tipranavir) of Human	
Immunodeficiency Virus Type 1 Isolates Derived from Patients with Multidrug	
Resistance to Other Protease Inhibitors. Antimicrobial Agents and	
Chemotheraphy, May 2000, pp. 1328-1332	
Stuyver, Lieven, et al. Line Probe Assay for Rapid Detection of Drug-Selected	
Mutations in the Human Immunodeficiency Virus Type 1 Reverse	
Transcripatase Gene. Antimicrobial Agents and Chemotheraphy, Feb. 1997, pp.	
284-291	
Toth, Mihaly V., et al. A Simple, Continuous Flurometric Assay for HIV Protease.	
Int. J. Peptide Protein Res. 36, 1990, pp. 544-550	
Tyagi, Suresh C., et al. Continuous Assay of the Hydrolytic Activity of Human	
Immunodeficiency Virus-1 Protease. Analytical Biochemistry 200, pp. 143-145	
(1992)	
Tyagi, Sanjay, et al. Multicolor Molecular Beacons for Allele Discrimination.	
Nature Biotechnology, January 1998, Volume 16, pp. 49-53	
Vasudevachari, M.B., et al. Emergence of Protease Inhibitor Resistance	
Mutations in Human Immunodeficiency Virus Type 1 Isolates from Patients	
and Rapid Screening Procedure for Their Detection. Antimicrobial Agents and	
Chemotherapy, November 1996, pp. 2535-2541, Vol. 40, No. 11	
Vergne, Lurence, et al. Genetic Diversity of Protease and Reverse Transcriptase	
Sequences in Non-Subtype-B Human Immunodeficiency Virus Type 1 Strains:	
Evidence of Many Minor Drug Resistance Mutations in Treatment-Naïve	
Patents. Journal of Clinical Microbiolog, November 2000, p. 3919-3925, Vol. 38,	
No. 11	
Wang, Gary T., et al. Design and Synthesis of New Fluorogenic HIV Protease	
Substrates Based on Resonance Energy Transfer. TetrahedronLetters, Vol. 31,	
o. 45, pp. 6496-6496	

Examiner	Date
Signature	Considered
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

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Page 1 of 1

Application Number	10/519,436
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First Named Inventor	Hendrika
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Examiner Name	Humphrey,
,	L.WZ
Attorney Docket Number	TIP 0015US

U.S. PATENT DOCUMENTS

		Name of Patentee or Applicant of Cited Document	U.S. Patent Docum	nent	Pages, Columns, Lines,	
Examiner Initials	Cite No.¹		Number	Kind Code ² (if known)	where relevant passages or relevant figures appear	

		FOREIG	N PATENT	DOCUMENT	<u>s</u>			
Examiner Initials	Cite No. ¹	Name of Patentee or Applicant of Cited Document	Foreign Pa	atent Documen Number⁴ K	indCode⁵	Pages, Columns, Lines, where relevant passages or relevant figures appear	T ⁶	
		OTHER PRIOR ART - N	ON PATENT	LITERATURE	DOCUMEN	ITS		
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		PCT Search Report dated January 4, 2005, International Application No. PCT/EP 03/50280						
PCT Search Report dated November 10, 2003,Internation Application No. PCT/EP 03/50277						003,International		
	Patent ApplicationUSSN 10/519,035 filed December 22, 2004 ((Docket No. TIP 0014 US) Patent Application USSN 518,525 filed December 22, 2004 (Docket No. TIP 0016 US)							

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